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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,262	08/05/2003	Alan M. Myers	ISU-003BX	7055
207	7590	01/24/2005	EXAMINER	
WEINGARTEN, SCHURGIN, GAGNEBIN & LEOVICI LLP TEN POST OFFICE SQUARE BOSTON, MA 02109			FOX, DAVID T	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 01/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/634,262	Applicant(s) MYERS ET AL.	
	Examiner David T. Fox	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 October 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's amendment of 25 October 2004 has obviated the objections to the specification set forth in the last Office action, except as follows. The Examiner apologizes for indicating that an error appeared at line 15 on page 16 of the specification. In fact, line 5 of that page contained the error, i.e. the recitation of "indicates" instead of ---indicated---. Applicant is requested to make the additional correction to line 5 of page 16. Additionally, Applicant is requested to amend the specification to insert a comma at the end of the last sentence of the top paragraph of page 9.

It is further suggested that Applicant amend the specification to reflect the actual figure numbering. Specifically, the following changes are suggested. Applicant is reminded that entire replacement paragraphs of the specification should be submitted in accordance with 37 CFR 1.121. The Examiner is merely indicating the particular changes that need to be made within each paragraph.

On page 9 of the specification, line 26, replace "Figure 1 shows" with ---Figures 1A-1B show---.

On page 10 of the specification, line 7, replace "Figure 2 shows" with ---Figures 2A-2C show---.

On page 10 of the specification, line 24, replace "Figure 3 shows" with ---Figures 3A-3B show---.

On page 11 of the specification, line 25, replace "Figure 5 shows" with ---Figures 5A-5C show---.

On page 12 of the specification, line 23, replace "Figure 6 shows" with ---Figures 6A-6B show---.

On page 12 of the specification, line 24, replace "Figure 6A shows" with ---Figures 6A-1 through 6A-3 show---.

On page 13 of the specification, line 13, replace "Figure 7 shows" with ---Figures 7A-7C show---.

On page 13 of the specification, line 20, replace "Figure 7B shows" with ---Figures 7B-1 through 7B-2 show---.

On page 14 of the specification, line 28, replace "Figure 9 shows" with ---Figures 9A-9C show---.

On page 15 of the specification, line 25, replace "Figure 11 shows" with ---Figures 11A-11B show---.

Applicant's submission on 06 December 2004 of a new Sequence Listing has obviated the objection thereto.

Applicant's Terminal Disclaimer filed 25 October 2004 has obviated the obviousness-type double patenting rejection.

Claims 1-10 (newly amended and newly submitted) are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the

inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1 and 8-10 recite that "about 450 amino acids" are encoded by "about nt 2425 to about nt 3791 of SEQ ID NO:1". However, there is no basis for either "about 450 amino acids" or "about" the recited nucleotide boundaries. Page 9 of the specification, lines 9-10 and page 28, lines 2-3 recite that a "nucleotide sequence comprising nt 2425 to nt 3791 of SEQ ID NO:1" encodes "amino acids 769 to 1225 of DU1", i.e. 457 amino acids. There is no mention of "about 450 amino acids", particularly as being encoded by the recited portion of SEQ ID NO:1. Similarly, there is no recitation of "about" nt 2425 to "about" nt 3791 of SEQ ID NO:1. Accordingly, the newly amended and newly submitted claims are directed to NEW MATTER.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, as stated on pages 3-5 of the last Office action for claims 1-7.

Claims 1-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, as stated on pages 5-7 of the last Office action for claims 1-7.

The claims remain free of the prior art, as stated on page 8 of the last Office action.

No claim is allowed.

Applicant's arguments filed 25 October 2004 have been fully considered but they are not persuasive.

Applicant urges that the written description rejection is improper, given the recitation in the amended claims of functional language, and the correction of the particular amino acid domain and nucleotide sequence encoding it.

The Examiner acknowledges that conserved catalytic and targeting domains of starch synthase enzymes are known. Thus, claims were allowed in parent application Serial No. 09/554,467 which only specified one particular nucleotide sequence domain, but also recited that the protein encoded by a nucleotide sequence comprising it have starch synthase activity (see, e.g., claim 2 of U.S. Patent 6,639,125.) However, the Examiner maintains that there is no description of the newly claimed amino acid domain or nucleotide sequence encoding it, as stated above. Furthermore, there is no description in the specification of the genus of all sequences with as low as 75% similarity thereto. No function associated with this particular 457 amino acid region has been disclosed, and only one species of the genus of all claimed sequence domains has been disclosed. Thus, neither prong of the two-prong *Lilly* test has been met.

Applicant urges that the enablement rejection is improper, given the claim amendments, and given the presentation of claims drawn to transformed products which are enabled.

The Examiner maintains that the claim amendments recite non-enabled sequence domains, as stated above. Furthermore, since the claimed nucleotide sequences encompass those which would produce inoperable proteins, there is no disclosed use for any product transformed therewith. Additionally, method claim 6 remains non-enabled. Thus, Applicant has not taught how to make or use the broadly claimed invention, including transformed products.

The following amendments would result in allowance of the application:

In claim 1, line 4 and lines 9-10, delete "about" and replace "450" with ---457---.

In claim 1, line 11, replace "75%" with "95%".

In claim 1, line 12, delete "about", both occurrences.

Cancel claims 8-10.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

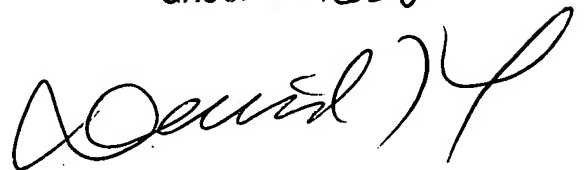
Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is 571-272-0795. The examiner can normally be reached on Monday through Friday from 10:30AM to 7:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy J. Nelson, Ph.D., can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

January 20, 2005

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1638

A handwritten signature in black ink, appearing to read "David T. Fox", with a large, stylized flourish extending from the end of the signature.